

### **DETAILED ACTION**

1. The amendment filed, 3/22/2011, is acknowledged. Claim 1 was amended. Claims 1-7 are pending in this application.

#### ***Election/Restrictions***

2. Applicant's confirmation of the election of Group I in the reply filed on 3/22/11 is acknowledged. During a telephone conversation with Steve Davis on Sept. 9, 2010 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-2. As a result, Claims 3-7 were and remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### **Withdrawn Rejections**

3. The rejection of claims 1-2, rejected under 35 U.S.C. 102(b) as being anticipated by Uematsu (JP2001278894), is hereby withdrawn in view of Applicants amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2 remain rejected under 35 U.S.C. 102(e) as being anticipated by Brophy (US20030060399 or US7135453).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to a peptide of the formula X1-X2-X3.

The reference teaches peptides of the sequence X1-X2-[X3-A(X4)APLP-X5]-n-X6, where X1 is absent or an aromatic ring, X2 is absent or a transduction domain, X3 the sequence WLR, X4 is S, T, Y, D, E, X5 is 0-3 amino acids, X6 is a transduction domain (see claim 1). The reference specifically teach numerous sequences that contain the sequence WLRRA(S,Y,T,D,E) (see pages 5-6). For example, the reference teaches the sequence WLRRASAP (see paragraph [0072]). Note that these sequences are specifically contemplated in the larger sequence above. The reference teaches that the peptides can be used to treat numerous disorders and discloses pharmaceutical formulations (see page 8). The reference anticipates the claimed invention.

### **Response to Applicants arguments**

Applicants argue that the claim language is closed by virtue of “consisting of” for the amino acid sequence. Applicants assert that while the instant claims allow for AP, the claims do not recite APLP.

Applicants arguments have been fully considered but have not been found persuasive.

The use of the transition language "consisting of" closes the claim to N- and C- terminal additions. However, the claim still recite "comprising language" with respect to the transduction domain. Thus the transduction domain may have additional amino acids so long as those additions do not destroy the characteristic of the transduction domains. In the instant case, the prior art teaches peptides of the sequence flagged on each side by the a transduction domain. The additional amino acids that comprise LP on the C-terminal end of X2 can be interpreted as part of the transduction domain. When interpreted in this light, the prior art anticipates the claimed invention.

Rejection is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 7,135,453. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a peptide of the formula X1-X2-X3.

The US patent claims peptides of the sequence X1-X2-[X3-A(X4)APLP-X5]-n-X6, where X1 is absent or an aromatic ring, X2 is absent or a transduction domain, X3 the sequence WLRR, X4 is S, T, Y, D, E, X5 is 0-3 amino acids, X6 is a transduction domain (see claim 1). The patent specifically claims X3 to be of the sequence WLRR (see claim 19) and X4 as S (see claim 18). Thus, the sequence claimed in the patent includes WLRRASAPLP. Note that while the US patent disclose a sequence that different from the claimed sequence in the addition of Lue and Pro at the terminal end, they still read on the instant claim since the instant claim do not utilize closed language for define X2. Since the US patent claims methods of treating disorders, in practicing the claimed method, one would have to utilize pharmaceutical formulations of the claimed peptides. Thus, the US Patent and the instant claims are not patentably distinct from each other.

6. Claims 1-2 remain directed to an invention not patentably distinct from claims 1-39 of commonly assigned US 7135453. Specifically, for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 7135453, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claims 1-2 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 7,381,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a peptide of the formula X1-X2-X3.

The US patent claims peptides of the sequence X1-X2-[X3-A(X4)APLP-X5]-n-X6, where X1 is absent or an aromatic ring, X2 is absent or a transduction domain, X3 the sequence WLRR, X4 is S, T, Y, D, E, X5 is 0-3 amino acids, X6 is a transduction domain (see claim 1). Thus, the sequence claimed in the patent includes WLRRASAPLP. Note that while the US patent disclose a

sequence that different from the claimed sequence in the addition of Luc and Pro at the terminal end, they still read on the instant claim since the instant claim do not utilize closed language for define X2. Thus, the US Patent and the instant claims are not patentably distinct from each other.

8. Claims 1-2 are directed to an invention not patentably distinct from claims 1-39 of commonly assigned US 71381699. Specifically, for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 71381699, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

#### **Response to Arguments**

For all of the double patenting rejections, Applicants raise similar arguments as recited under anticipation Brophy (US20030060399 or US7135453). As stated above, Applicants argue that the

claim language is closed by virtue of "consisting of" for the amino acid sequence. Applicants assert that while the instant claims allow for AP, the claims do not recite APLP.

Applicants arguments have been fully considered but have not been found persuasive.

The use of the transition language "consisting of" closes the claim to N- and C- terminal additions. However, the claim still recites "comprising language" with respect to the transduction domain. Thus the transduction domain may have additional amino acids so long as those additions do not destroy the characteristic of the transduction domains. In the instant case, the prior art teaches peptides of the sequence flagged on each side by the a transduction domain. The additional amino acids that comprise LP on the C-terminal end of X2 can be interpreted as part of the transduction domain. When interpreted in this light, the prior art anticipates the claimed invention.

Rejection are maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
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